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APPLICATION NO. 09/518,562	FILING DATE 02/22/00	FIRST NAMED INVENTOR HOUSEY	ATTORNEY DOCKET NO. 395/35
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HM22/0226

EXAMINER SAUNDERS, D
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ART UNIT 1644	PAPER NUMBER 15
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DATE MAILED: 02/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

510,562

Applicant(s)

HOUSET

Examiner

SAUNDERS

Group Art Unit

1044

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/7/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 33-34, 36-40, 42-50, 52-86 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 34-34, 36-37, 43-50, 59-65, 71-78 is/are allowed.
- ☒ Claim(s) 39-40, 42, 52-58, 66-70, 79-86 is/are rejected.
- ☒ Claim(s) 38 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 12
- ☐ Notice of References Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Acti n Summary

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The amendment of 12/7/00 has been entered.

The claims pending and under examination are 33-34, 36-40, 42-50 and 52-86 are pending and under examination.

Applicant's amendment has overcome the previously stated rejection under 112, second paragraph..

Claims 66, 70, 79 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims contain new matter by reciting "interacts intracellularly with the enzyme", which does not appear as a descriptive phrase in the original disclosure.

Applicant's urging that page 13 of the specification lists several examples of enzymes that happen to have the property of being ones that would interact "intracellularly" with the agent is not convincing. By now reciting these feature applicant is carving out a new subgenus of methods involving an "intracellular" interaction, which is a feature that was not definitively pointed out by applicant at the time of filing as a defining aspect of the invention. The fact that applicant has recited a few species of enzyme that would be involved in such an interaction does not provide support for the newly recited subgenus.

Applicant is advised that should claims 42 and 58 are be found allowable, claims 69 and 80, respectively will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both

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cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 38 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 63. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Due to applicant's urgings of 12/7/00, the previously stated rejection under 102/103 over Escobedo et al. or Williams et al. has been withdrawn.

The following art is newly cited.

Claims ~~39-40, 42, 52-58, 67-70~~ and ~~80-86~~ are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans (4,981,784).

Evans et al. corresponds to EP 0,325,849, discussed as reference AAA in the European opposition of Boehringer Ingelheim (translation filed with the IDS of 12/7/00).

The disclosure of the reference that is relied upon dates to the 12/2/87 filing date of its parent application 07/128,331.

Evans et al. show assays (cols. 11, 12, 14) for functional ligands (which are inherently "activators" or inducers) of the biological activity of the retinoic acid receptor (RAR) protein. The protein is overexpressed in a cell by insertion of a coding sequence for the receptor in a

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vector which is used to transform the cell. See col. 10, lines 14-20. A second test cell or control cell, transformed with the parent vector, may be employed for the purposes of comparison (col. 14, lines 48-52). Ligand - receptor interactions occur intracellularly (col. 5, lines 49-55). The effect of various "chemical agents" or test ligands upon these cells is described at col. 14, lines 40-67 and in Fig. 3A. The assay read-out of CAT activity may be properly considered a "phenotypic response" which can be graded as a percent of maximum induction (see left axis of Fig. 3A).

The examiner thus considers claims 39-40, 42, 52-54, 56, 58, 67-70, 80-82, 84 and 86 are clearly shown in the reference, when the broadest reasonable interpretations are given to the claim recitations. The comparison limitation recited in claims 55, 57, 83 and 86 are conventional in the cellular testing art; and in fact, Fig. 3A may be considered to show the limitation of claim 55 in a practical sense since the lowest concentrations of the ligand employed do not stimulate a response and thus essentially correspond to a non-treatment of the cells.

Documents filed in an IDS on 12/7/00 have been considered. Applicant has not listed these on a Form PTO-1449. Therefore these have not been acknowledged. Furthermore they are not proper references since they are not publications.

